UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL No. 1456** **Master File No. 01-12257-PBS** **Judge Patti B. Saris**
THIS DOCUMENT RELATES TO: **State of California, *ex rel.* Ven-A-Care v. Abbott Laboratories, *et al.*** **03-cv-11226-PBS**	

PLAINTIFFS' SUR-REPLY TO DEFENDANTS' MOTION TO DISMISS THE FIRST AMENDED COMPLAINT

INTRODUCTION

None of Defendants' arguments in their Reply establish any basis on which this Court should dismiss the First Amended Complaint (FAC) under Rules 12(b)(6) or 9(b) of the Fed. R. Civ. P.

ARGUMENT

I. DEFENDANTS' DECISIONS TO HAVE THEIR DRUG PRODUCTS REIMBURSED BY MEDI-CAL IMPOSED DUTIES NOT TO MISLEAD THE GOVERNMENT.

Plaintiffs have alleged, under the California False Claims Act (CFCA), that Defendants systematically damaged California's Medi-Cal Program. They did so by reporting false information about their drug's prices, including Average Wholesale Price (AWP) and Direct Price (DP), causing Medi-Cal to reimburse providers at inflated amounts, e.g., when reimbursement was set at AWP, DP, the Federal Upper Limit (FUL) or the Maximum Allowable Ingredient Cost (MAIC). Defendants also created unlawful financial remuneration, or kickbacks, to induce healthcare providers to purchase, dispense or administer the drugs. The FAC states the drugs at issue, the false prices the Defendants caused to be reported, and facts supporting the allegations that the information was false and that the Defendants knew it was false.

Defendants attempt to buttress their motion to dismiss through improper reference to purported "facts" outside the FAC, which are vigorously disputed. Defendants - disregarding Rule 12(b)(6) standards - invite the Court to (1) adopt their interpretative version of the significance of these disputed facts, (2) conclude that California somehow embraced Defendants' conduct, and (3) thereby insulate Defendants from responsibility for their actions. At most, Defendants' attempted

foray beyond the four corners of the FAC raises questions properly directed to the trier of fact.[1]

Defendants correctly state that California chose to use reported AWP as a basis for Medi-Cal pharmaceutical reimbursement. Having done so, California was entitled to rely on the truthfulness of information submitted pertaining to that reimbursement system. Contrary to Defendants' insinuations, neither the wisdom nor the reasonableness of the government's conduct is at issue in the FAC. The Defendants do not, and cannot, point to any legal authority remotely supportive of their apparent posture in this case: that government public health care programs must preemptively detect and cure fraud committed by those enjoying the benefits of program expenditures, or risk immunizing those who perpetuate the fraud. "The suggestion that Congress [or California] would deliberately condone a bribery scheme using public funds to enrich drug manufacturers and physicians is, to say the least, unusual." *In re Lupron Mktg. & Sales Practices Litig.*, 295 F. Supp. 2d 148, 182 (D. Mass. 2003). Those dealing with government programs undertake an enhanced duty of truthfulness, such as that reflected in the definition of "knowledge" in the California and federal False Claims Acts. The Medi-Cal Program is just such a government program, one based upon trust: here, a trust imposed on drug manufacturers who constitute a privileged and lucrative industry.

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[1] Under Rule 12(b), "any consideration of documents not attached to the complaint, or not expressly incorporated therein, is forbidden, unless the proceeding is properly converted into one for summary judgment under [Fed. R. Civ. P.] 56." *Watterson v. Page*, 987 F.2d 1, 3 (1st Cir.1993). *See also* FED. R. CIV. P. 12(b) (if "matters outside the pleading are presented to and not excluded by the court, the motion shall be treated as one for summary judgment and disposed of as provided in Rule 56"). Moreover, upon decision to convert the motion to one for summary judgment, "all parties shall be given a reasonable opportunity to present all material made pertinent" by the conversion decision. FED. R. CIV. P. 12(b). When discovery has barely begun and the nonmovant has had no reasonable opportunity to obtain and submit additional evidentiary materials to counter the movant's materials, conversion of a Rule 12 motion to a Rule 56 motion is inappropriate. *Gay v. Wall*, 761 F.2d 175, 177-78 (4th Cir. 1985).

II. NONE OF THE COUNTS IN THE AMENDED COMPLAINT ARE VULNERABLE TO RULE 12(b)(6) DISMISSAL.

A. The FAC amply alleges falsity under the California False Claims Act.

Defendants insist the FAC fails to allege any of the elements of falsity requisite to a false claim. A review of the FCA demonstrates otherwise, as set forth below.

1. Plaintiffs Have Sufficiently Alleged The Submission Of A False Claim.

The gravamen of Plaintiffs' FAC is that Defendants made false statements in order to enhance the reimbursement for their drugs, and that Defendants' conduct caused the submission of false claims to California's Medi-Cal program. CAL. GOV'T CODE §§ 12651(a)(1) and (2). Although Defendants concede that Plaintiffs have alleged the submission of false claims in 125 paragraphs of the FAC, they now argue that "none of these paragraphs describes a false claim." *See* Reply at 5 (emphasis added). Defendants are wrong.

First, Defendants fail to address two cases from this Court cited by Plaintiffs. *See* Opp. at 10. Both cases concern motions to dismiss in the context of fraudulent drug pricing schemes that are virtually identical to the one alleged in the FAC. In *Massachusetts v. Mylan Laboratories,* 357 F. Supp. 2d 314 (D. Mass. 2005), Massachusetts alleged that defendants supplied drug pricing information in the form of Wholesale Acquisition Cost ("WAC") and AWP to third party publishers, but that the published prices did not "reflect actual average prices paid by wholesalers or providers for drugs." *Id.* at 320. This Court denied defendants' motion to dismiss the Massachusetts FCA counts, finding that defendants had "misrepresent[ed] their true prices to the government." *Id.* at 322. Similarly, in *In re Lupron,* the Court denied a motion to dismiss RICO claims linked to defendants' alleged "deliberate inflation of AWPs." *In re Lupron*, 295 F. Supp. 2d at 160. Judge

Stearns determined, in particular, that among the most telling acts of alleged fraud was defendants' publication of inflated AWPs in the Red Book. *Id.* at 171. The publication of false AWPs, as alleged in the FAC, would plainly constitute the "making of false statements" under the CFCA. *See United States ex rel. Franklin v. Parke-Davis,* 2003 WL 22048255, *1 (D. Mass. 2003) (*Parke-Davis II)*(sustaining FCA allegations although no false information appeared on face of claim forms).

Second, Defendants themselves readily admit that they have adequate notice that the false claims at issue are those "claims submitted by providers to Medi-Cal for reimbursement," citing FAC paragraph 42, which specifically alleges: "Defendants' inflation of their reported prices caused many, if not most, claims paid by Medi-Cal for Defendants' specified prescription drugs to be false claims." FAC ¶ 42. Plaintiffs have sufficiently pleaded facts showing that claims were submitted by Medi-Cal providers, and payment of those claims at inflated amounts was based upon information reported by Defendants as part of a fraudulent course of conduct.

2. Defendants Reported False Average Wholesale Prices and Direct Prices to the National Compendia.

Defendants insist that California has not alleged that the AWPs and DPs reported by Defendants and published by First Data Bank (FDB) were false. *See* Reply at 6. But California has done just that. For example, the FAC alleges that because of the false AWP reported by Defendants and published by FDB, "[the California's Department of Health Services (DHS)] price reimbursed to providers for [MYLAN's] Atenolol 50 Mg tablets is 4235% of the contract price paid by providers." FAC ¶ 124; see also FAC ¶ 172. ("DHS's price paid to the provider for the WARRICK inhaler is 351% of the contract price paid by providers.") In these and other examples set forth in the FAC and its sealed exhibits, Defendants have reported prices that bear "no good faith

relationship to any true prices in the marketplace." FAC ¶ 82. Taking as true California's well pleaded facts, and extending California every reasonable inference in its favor, *see United States ex rel. Franklin v. Parke-Davis,* 147 F. Supp. 2d 39, 50 (D. Mass. 2001)(*Parke-Davis I*), Defendants cannot explain how reporting an "average wholesale price" that is 4235% of a provider's cost is anything but a false and fraudulent statement.

Contrary to Defendants' assertions, California is not seeking an "alternative definition" of the term "average wholesale price," and the crux of California's theory within the FAC concerning Defendants' inflated AWPs is not lost merely because California draws its AWP from a nationally published compendium. Indeed, California is hardly alone in relying on Defendants' reporting of AWP and DP to the national compendia.[2]

Defendants continue to misconstrue the import of several cases involving ambiguous statutes or regulations. In *United States ex rel. Cox v. Iowa Health System*, 29 F. Supp. 2d 1022 (S.D. Iowa 1998), defendants argued that the term "Patient Loaded Miles" as used in the federal statute could mean either statute miles or nautical miles, and the court agreed that a common usage 5,280 foot mile was not fraudulent. *Id.* at 1024-26. In *United States ex rel. Gathings v. Bruno's, Inc.*, 54 F. Supp. 2d 1252 (M.D. Ala. 1999), defendants argued that the term "the provider's usual and customary charge to the general public" means the "retail" charge rather than the "third-party payer" charge for defendants' services. *Id.* at 1526. Here, however, no reasonable interpretation of

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[2] At present, statutes in Arkansas (A.C.A. § 20-76-502(1)), the District of Columbia (DC ST § 48-831.02(2)), Illinois (320 ILCS 55/15 § 15), Louisiana (LSA-R.S. 22:250.51), Maine (22 M.R.S.A. § 2681), Montana (MCA 53-6-1001), New York (McKinney's Social Services Law § 367-a.9.(b)(ii)), Oklahoma (85 Okl. St. Ann. §14 F.6.) and Vermont (33 V.S.A. § 2005a(d)(1)) define AWP by reference to national compendia, while Ohio (R.C. § 173.061(E)(4)(d)), Connecticut (C.G.S.A. § 17b-280(a)(2)) and Florida (F.S.A. § 409.908(14)) use the term AWP without reference or definition. Many of these states are suing one or more of the Defendants named in the FAC for having reported inflated AWPs, indicating those states also do not interpret the term AWP in the manner urged by Defendants in their Motion to Dismiss.

California's regulations supports Defendants' position. In *United States ex rel. Oliver v. Parsons Co.*, 195 F.3d 457 (9th Cir. 1999), the Ninth Circuit rejected the "proposition that a 'reasonable interpretation' of a regulation precludes falsity," explaining:

> [T]his case involves regulations that, while unquestionably technical and complex, are not discretionary. . . it is Parsons' compliance with these regulations, as interpreted by this court, that determines whether its accounting practices resulted in the submission of a "false claim" under the Act.

Id. at 463 (footnote omitted). *See also United States v. Estate of Rogers*, 2001 WL 818160, *4 (E.D. Tenn. 2001)(same). Assuming arguendo the applicable laws and regulations are ambiguous, the trier of fact must be permitted to determine the Defendants' knowledge in light of any such ambiguity.

Here, Defendants knew that the State's Medicaid program was attempting to estimate acquisition costs based on prices generally and currently available, yet they each took action to cause these estimates to be grossly inflated. Such conduct, by key participants in the delivery of prescription drugs to Medi-Cal beneficiaries, is clearly not a reasonable response to allegedly ambiguous regulations. No reasonable reading of the applicable law could lead a drug company to believe it had a right to use scarce Medicaid dollars as its private marketing fund, from which to arrange financial inducements for its customers.

3. Defendants Fail To Meet The High Standard Applicable To Arguments That "Government Knowledge" Bars A False Claims Prosecution.

Defendants' "government knowledge" argument is crippled by an incorrect understanding of the standard established by the courts in analyzing the import of government knowledge in false claims cases. Moreover, Defendants' assertion that "[t]here can be no liability under the CFCA where, as here, the State has knowledge of the pertinent facts," *see* Reply at 9, is simply wrong.

The government knowledge bar, when it is applied, generally operates within cases involving contract deviations or deviations from regulatory requirements, as noted below. Here, there is no claim that Defendants engaged in any disclosure or negotiations with DHS about the proper reporting of AWP or DP. At most, government knowledge may be relevant to the scienter, *i.e.* whether a defendant "knowingly" presents a false claim to the agency. But it is not an automatic ticket to Rule 12(b)(6) dismissal of a false claims action, as Defendants simplistically assert, and it is rarely an issue that is resolved on a motion to dismiss due to its intrinsically fact-intensive nature. As the Ninth Circuit explained in *United States ex rel. Hagood v. Sonoma County Water Agency*, 929 F.2d 1416 (9th Cir. 1991), expressly rejecting the argument that government knowledge of the falsity of a claim automatically bars an FCA action, "[t]he requisite intent is the knowing presentation of what is known to be false. That the relevant government officials know of the falsity is not in itself a defense." *Id.* at 1421 (citing *United States v. Ehrlich*, 643 F.2d 634, 638-39 (9th Cir. 1981)). *See also United States ex rel. Kreindler & Kreindler v. United Technologies Corp.*, 985 F.2d 1148, 1156 (2nd Cir. 1993)("[W]e agree with *Hagood* that the statutory basis for an FCA claim is the defendant's knowledge of the falsity of its claim, see [31 USCA] § 3729(a) & (b), which is not automatically exonerated by any overlapping knowledge by government officials.")

Defendants' defective appraisal of the legal significance of the government knowledge inquiry rests on three contract-deficiency cases, each inapposite to the allegations pleaded in the FAC. In each, the defendant-contractor's deviation from specifications or regulations had been *voluntarily disclosed and approved by the government in advance*. In *American Contract Services v. Allied Mold & Die, Inc.*, 94 Cal. App. 4th 854 (2001), the court found that the government's termination of a bidding process and sole sourcing of the contract (in violation of its own

administrative regulations) insulated the contractor from CFCA allegations focusing on deviations from contracting practices. *See id.* at 864-65 (dismissing Complaint on motion of the Attorney General). Next, Defendants rely on *United States ex rel. Durcholz v. FKW Inc.*, 189 F.3d 542, 545 (7th Cir. 1999), where the defendant-contractor submitted bills for dredging work under an "excavation" line item at the express direction of the government. "We decline to hold FKW liable for defrauding the government by following the government's explicit directions." *Id.* at 545 (footnote omitted). Finally, Defendants point to *United States ex rel. Butler v. Hughes Helicopters, Inc.*, where the "government's knowledge and accession at every turn" in modifying aircraft testing specifications defeated any inference that the contractor had knowingly presented false claims in its helicopter test reports. *See* 71 F.3d 321, 326 (9th Cir. 1995). None of these cases bear on this Court's instant evaluation of the FAC's detailed description regarding Defendants' actions in inflating reimbursements to drug provider customers, which were undertaken without the California Medicaid agency's approval or direction. The FAC alleges that Defendants explicitly communicated to *providers* dispensing their drug – but certainly never to the California DHS – about the attractive spreads between AWP and actual provider prices. FAC ¶¶ 43-47.[3] And nothing in the FAC suggests the state agency's "knowledge and accession at every turn," *Butler*, 71 F.3d at 326, concerning Defendants' actions in falsely inflating the prices they reported to the compendia.

B. Defendants' Alternative Rule 12(b)(6) Arguments Also Fail.

[3] Defendants' unsupported assertions regarding "negotiations for supplemental rebates" (*see* Reply at 10, and 3 n. 2), are misplaced in the procedural posture of this case. There is no reference to any such negotiations in the FAC, and there is no evidence to identify which defendants, for which drugs, or whether any information purportedly provided to DHS was accurate. The cited regulation (*see* id. at 3, n.2) merely provides that DHS *may* enter into contracts. CAL. WEL. & INST. CODE § 14105.33(a). In fact, supplemental rebate agreements were uncommon for generic drugs. Defendants' statement that California was "[a]rmed with that information," Reply at 10, is both wrong and unsupported.

1. Defendants Caused To Be Presented A False Claim As Alleged in Counts I and IV.

Defendants disingenuously posit the theory that false claims liability is barred because "Plaintiffs have not alleged any connection at all" between Defendants' submission of false prices to the compendia and the claims submitted by providers for Defendants' drugs which were reimbursed at the same inflated prices. *See* Reply at 12. But that connection is alleged in considerable detail in the FAC (*see* ¶¶ 27, 30, 32-40, 42-45 and 48), which explains how providers are reimbursed for Defendants' drugs based on a reimbursement system which relies on prices reported by Defendants for their drugs. When Defendants insist they "have no control, whatsoever, over what providers submit in those claims," they obligingly underscore in stark relief one of the key contentions explicitly alleged in the FAC: that Defendants have *exclusive control* over the core data at issue in the FAC, i.e., the data documenting the extent of the gulf between the inflated prices Defendants reported to the compendia and on which - as they always knew - DHS reimbursed providers submitting claims for reimbursement on Defendants' drugs, and the actual prices at which those drugs were sold in the marketplace. *See* FAC ¶¶ 43-47.

Defendants' argument rests, inter alia, on a misguided attempt to distinguish this Court's two prior rulings in the *Parke-Davis* cases. Defendants do not dispute that *Parke-Davis I* and *Parke-Davis II* set forth the correct test for causation under the FCA: *i.e.*, whether the "defendant's conduct was 'a substantial factor in producing the harm'." *Parke-Davis II,* 2003 WL 22048255 at *6. But nothing in the *Parke-Davis* cases suggests that this Court limited its holding to the specific scenario urged by Defendants, *i.e.*, only in those instances when defendants "coach[] providers on how to fill out Medi-Cal forms." *See* Reply at 12.

Defendants' reliance upon *United States ex rel. Kinney v. Hennepin County Med. Ctr.*, 2001 WL 964011 (D. Minn. 2001) is misplaced. Plaintiffs herein allege that Defendants played a key role in the events that led to the false claims, *i.e.*, they controlled and reported false and inflated prices to the compendia with knowledge that they would be used by the Medi-Cal program to reimburse providers. FAC ¶¶ 34, 42. At the same time, Defendants were routinely aware of and often controlled the actual acquisition costs of the providers. FAC ¶ 45. Unlike the passive role that the physicians played in *Kinney* because of the computerized accounting system that automatically coded ambulance runs as medically necessary regardless of the physicians' determinations, *Kinney,* 2001 WL 964011 at *10, Defendants were not innocent bystanders.

Defendants' argument regarding an intervening force, *see* Reply at 12, would negate the express statutory inclusion of "causes a claim to be submitted." Obviously, the CFCA, like the federal False Claims Act (FCA), is intended to impose liability in instances where someone other than the defendant submitted the actual claims, a proposition firmly established for decades: "Without question, the [FCA is] broad enough to 'reach any person who knowingly assisted in causing the government to pay claims which were grounded in fraud, without regard to whether that person had direct contractual relations with the government.'" *United States v. Taber Extrusions LP*, 341 F.3d 843, 845 (8th Cir. 2003), quoting *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 544-45 (1943); *see also United States ex rel. Riley v. St. Luke's Episcopal Hosp.*, 355 F.3d 370, 378 (5th Cir. 2004) (same). Finally, determination of causation on a motion to dismiss is premature and, hence, should not be the basis upon which to grant a motion to dismiss. *Parke-Davis II,* 2003 WL 22048255 at *2.

2. Defendants Are Subject to Liability Under California Government Code section 12651(a)(8) Because They Benefitted From Their False Reporting of Wholesale Drug Prices.

Defendants argue Count III fails because they are neither "beneficiaries" nor "discovered" any false claims. *See* Reply at 13. Defendants seem to argue they cannot be alleged to have "discovered" the falsity of a claim generated through their own conduct. Plaintiffs do not "candidly admit" (*id.*) to Defendants' interpretation of "discovers." Because Defendants knew of the inflated AWPs and DPs, which set reimbursement on their products, they had perforce already "discovered" their own conduct.

Defendants also argue that the word "beneficiary" in Section 12651(a)(8) "cannot be read as anyone who indirectly benefits from a government payment," because that reading would sweep so broadly as to inculpate anyone "who may possibly benefit from the act." *See* Reply at 13. In urging their cramped reading of "beneficiary," Defendants wrongly ignore the "widest possible" reading intended by the courts in interpreting the CFCA as well as the FCA, on which the CFCA is based. *LeVine v. Weis*, 90 Cal. App. 4th 201, 210 (2001). Moreover, because the CFCA is very similar to the federal FCA, federal precedents apply in interpreting it. *City of Pomona v. Superior Court*, 89 Cal. App. 4th 793, 801-802 (2001). In turn, the FCA's reach extends to "any person who knowingly assisted in causing the government to pay claims which were grounded in fraud." *Hess,* 317 U.S. at 544. Accordingly, in *United States v. Veneziale,* 268 F.2d 504 (3rd Cir. 1959), the court concluded "[w]e are satisfied that the government, having been compelled to pay an innocent third person as a result of the defendant's fraud in inducing the undertaking, is entitled to assert a claim against the defendant under the False Claims Act." *Id.* at 505-06. And in *United States v. Incorporated Village of Island Park*, 888 F. Supp. 419 (E.D.N.Y. 1995), the court explained:

> When claims for payment on those mortgages are submitted by the innocent mortgagees, the fraudulent course of conduct pursuant to which the mortgages were approved emerge in "full vigor" and become a part of those claims, which therefore constitute false claims within the meaning of the False Claims Act. *It is irrelevant that Lend-Mor, the lender who submitted the claims for mortgage subsidies*[,] *is totally innocent.*

Id. at 440 (emphasis added).

3. Counts IV and V Satisfactorily State CFCA Claims.

In support of their preemption argument, the Defendants point to *State v. Harden*, 873 So. 2d 352, 355 (Fla. Dist. Ct. App. 3d Dist. 2004), a case explicitly questioned by a different panel of the same court in *State v. Wolland*, 902 So. 2d 278 (Fla. Dist. Ct. App. 3d Dist. 2005). *See* Reply at 14. The Florida state court decisions do not outweigh the strong presumption against federal preemption in this case.[4] *Wolland* made clear that the Florida court's only basis for finding Florida's Medicaid Anti-Kickback statute (AKS) preempted was the lack of a "safe harbor" provision[5] similar to the federal statute's and which *is* included in the California statute.[6] And in a final attempt to dissuade this Court from applying the strong presumption against preemption, the Defendants erroneously claim that Plaintiffs have "conceded" that the safe harbor provisions of the federal AKS are broader than California's. But no such concession was made.[7]

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[4] This Court has held: "[T]he presumption against federal preemption applies to state fraud statutes that are used to reduce the inflated drug costs to the state Medicaid program . . . Medicaid is the paradigmatic program of cooperative federalism . . . states have historically played a significant role in investigating and prosecuting Medicaid fraud." *In re Pharm. Indus. Average Wholesale Price Litig.*, 321 F. Supp. 2d 187, 198 (D. Mass. 2004) (internal citation omitted).

[5] *State v. Wolland*, 902 So. 2d 278, 286.

[6] Compare the former FLA. STAT. § 409.920 (2002) with CAL. WEL. & INST. CODE § 14107.2 (c)(2).

[7] *See* CAL. WEL. & INST. CODE § 14107.2(c)(1)-(2) and 42 USCA § 1320a-7b(b)(3). Both statutes contain a safe harbor for properly disclosed discounts. Defendants have nowhere explained their assertion that California's safe harbor provisions are "narrower" than the federal statute or how their alleged conduct would have been permitted under either law. The Defendants are alleged in the FAC to have created and marketed their inflated reimbursement spreads, knowing that their kickbacks would be concealed from Medi-Cal. *See* FAC, Counts IV and

Also, contrary to the Defendants' assertions, the FAC clearly alleges the remuneration was concealed from Medi-Cal. *See, e.g.*, FAC ¶¶ 192, 193, 194, 198, 199, 200. Defendants also argue the FAC fails to adequately allege how their AKS violations rise to a CFCA claim, citing *United States v. Duz-Mor Diagnostic Laboratory, Inc.*, 650 F.2d 223, 227 (9th Cir. 1981) for the proposition that reporting falsely inflated prices to the compendia does not qualify under the AKS because those acts are not an "offer" or "payment." (Rep. at 14.) *Duz-Mor* is inapposite since the statement on which Defendants rely actually concerns the Ninth Circuit's rejection of *Duz-Mor's* strained contracts-based interpretation of "offer" in favor of one well-established within the context of federal bribery prosecutions. *See Duz-Mor*, 650 F.2d at 227.

Defendants next attempt to recast Plaintiffs' CFCA claims in Counts IV and V by mis-characterizing them as "implied certification" theories that cannot give rise to false claims act liability, while incorrectly describing the treatment of such theories by the courts.[8] First, the FAC - which speaks for itself - alleges the claims in question were false claims because they would not have been paid in the inflated amounts but for the Defendants' violations of the California AKS, and certainly not had the fact of the inflated remuneration been properly disclosed. *See, e.g.*, FAC ¶¶ 191, 197, 198. Second, even if Plaintiffs had explicitly recited the words "implied certification" in

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V.

[8] While the defense argument on this point is a bit unclear, Defendants appear to contend that the Plaintiffs are obligated to allege the title or legal description given to such claims by the courts when the Defendants note that the words "implied certification" do not appear in the FAC. The Plaintiffs have plead the ultimate facts which, if proven, will establish their CFCA claims based on violations of the California Anti-Kickback Statute. (*See* FAC Counts IV and V.) Defendants are clearly on notice of the legal premise for these allegations, and Plaintiffs have pleaded facts which, if proven, will establish their CFCA claims based on violations of the California Anti-Kickback Statute. (See FAC Counts IV and V.) "Implied certification" is merely the description given to claims that are false because they are submitted or caused to be submitted by a defendant who knows that the required conditions for payment have not been met, including required compliance with applicable laws and regulations. *See, e.g., McNutt v. Haleville Medical Supplies Inc.*, 423 F. 3d 1256, 1259 (11th Cir. 2005); *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 239, n.6 (3d Cir. 2004).

Counts IV and V, Defendants wrongly cite two cases for the purported proposition that the implied certification theory has been judicially rejected in connection with anti-kickback statutes. *See* Reply at 15-16. They mischaracterize *United States ex rel. Barmak v. Sutter Corp.*, 2002 WL 987109 (S.D.N.Y. May 14, 2002) as "explicitly rejecting" the implied certification theory, and then cite *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 785 (4th Cir.1999) for the same premise. The actual significance of those two cases is explained in *United States ex rel. Pogue v. Diabetes Treatment Centers of America, Inc.*, 238 F. Supp. 2d 258 (D.D.C. 2002), which first describes the statement in *Barmak* as *dicta* because the implied certification issue was not briefed, having been raised *sua sponte*, then notes that the *Harrison* court merely raised the issue in a footnote while expressly reserving the question for a later time. *Pogue*, 238 F. Supp. 2d at 264-65 (emphasis added). As this Court has stated, it "agrees with the government that recent case law supports implied-certification FCA claims in the healthcare context, including kickback-based claims." *Parke-Davis II,* 2003 WL 22048255 at *7.

C. Plaintiffs State a Claim For Drugs Reimbursed on FULs and MAICs.

Defendants insist that any claims predicated on drugs reimbursed at a FUL or a MAIC must be dismissed because the FAC fails to connect AWPs and DPs to the calculation of FULs and MAICs, and no Defendant could increase market share by manipulating FUL or MAIC. *See* Reply at 17. Defendants are presumably aware that a FUL "is based on all listings contained in current editions (or updates) of published compendia of cost information for drugs available for sale nationally." 42 C.F.R. § 447.332, subd. (a)(1)(ii). If the FUL was set based on inflated AWPs, it was set higher than it would have been if Defendants had reported non-inflated AWPs or DPs.

The Myers and Stauffer report found that for drugs reimbursed at FULs, the provider

pharmacies surveyed paid an average of just 12.7% of the AWP and 38.7% of the FUL. FAC Exh. 12, at 4. Had Defendants' AWPs not been falsely inflated, they would often have been lower than the MAICs and would have set the reimbursement price. The FAC and its exhibits document the common virulence which comprehensively infected California's Medi-Cal reimbursement system - *i.e.*, inflated AWPs and DPs - and no sector of the reimbursement system was immune from that infection no matter which element of the reimbursement standard was employed.

D. All Counts of the First Amended Complaint Satisfy the Pleading Requirements of Rule 9(b).

Defendants' arguments concerning Rule 9(b) in their Reply Memorandum add little to those previously stated in their Motion to Dismiss. Plaintiffs have alleged with the requisite specificity that each Defendant knowingly caused the submission of false claims to the government by making false pricing representations to FDB with knowledge that Medi-Cal used these reported prices to establish and pay reimbursement amounts on claims for Defendants' drug products. FAC ¶¶ 49-176. Plaintiffs have clearly stated the "who, what, when, where, and how" of the fraudulent submissions that Defendants caused to be made. FAC ¶¶ 4-22, 43, 44, 49. Further, Plaintiffs have explicitly alleged that false claims were indeed submitted to the government. FAC ¶ 42. And Plaintiffs have clearly satisfied the test set forth in *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 232 (1st Cir. 2004) by providing details that identify the particular false claims that were submitted to the government in the exhibits attached to the FAC.

CONCLUSION

Defendants' Motion To Dismiss should be denied in all respects. In the alternative, should this Court dismiss any claims within the FAC, Plaintiffs should be granted leave to amend.

Respectfully submitted,

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Dated: April 17, 2006

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CERTIFICATE OF SERVICE

I, Nicholas N. Paul, hereby certify that on April 17, 2006, I caused a true and correct copy of the foregoing, **PLAINTIFFS' SUR-REPLY TO DEFENDANTS' MOTION TO DISMISS THE FIRST AMENDED COMPLAINT** to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

Dated: April 17, 2006

/s/ Nicholas N. Paul
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